What is Claimed is:

1. A pharmaceutical composition comprising an oral transmucosal solid dosage form comprising an ionizable pharmaceutical agent, a buffer, and a pharmaceutically acceptable excipient, wherein said composition is substantially sugar-free and is bioequivalent to a sugar-containing oral transmucosal solid dosage form, and wherein said buffer is present in an amount sufficient to maintain a portion of said pharmaceutical agent, upon dissolution of said dosage form in saliva, in an ionized state.

2. The composition according to Claim 1, wherein said sugar-containing transmucosal solid dosage form contains a sugar selected from the group consisting of glucose, mannose, galactose, ribose, fructose, maltose, sucrose, lactose, and combinations thereof.

3. The composition according to Claim 1, wherein said pharmaceutically acceptable excipient comprises a polyhydric alcohol.

4. The composition according to Claim 3, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof.

5. The composition according to Claim 4, wherein said polyhydric alcohol is sorbitol.

6. The composition according to Claim 4, wherein said polyhydric alcohol is mannitol.

7. The composition according to Claim 4, wherein said polyhydric alcohol is xylitol.

8. The composition according to Claim 4, wherein said polyhydric alcohol is erythritol.

9. The composition according to Claim 4, wherein said polyhydric alcohol is maltitol.

10. The composition according to Claim 4, wherein said polyhydric alcohol is lactitol.

11. The composition according to Claim 4, wherein said polyhydric alcohol is isomalt.

12. The composition according to Claim 4, wherein said polyhydric alcohol is a combination of mannitol and polyalditol; xylitol and polyalditol; isomalt and polyalditol; mannitol and sorbitol; xylitol and sorbitol; and isomalt and sorbitol.

13. The composition according to Claim 4, wherein said polyhydric alcohol is a combination of isomalt and polyalditol.

14. The composition according to Claim 4, wherein said polyhydric alcohol is a combination of isomalt and sorbitol.

15. The composition according to Claim 1, wherein said excipient comprises a polyhydric alcohol and further comprising a binding agent.

16. The composition according to Claim 15, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof; and said binding agent is selected from the group consisting of polydextrose, cellulosic ether, and polyethylene glycol.

17. The composition according to Claim 15, wherein said polyhydric alcohol is isomalt and said binding agent is selected from the group consisting of polydextrose, hydroxypropyl cellulose, and polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 3350 to 20,000.

18. The composition according to Claim 15, wherein said polyhydric alcohol is isomalt and said binding agent is polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 4000 to 8000.

19. The composition according to Claim 1, wherein said excipient comprises a non-cariogenic mono-, di-, oligo-, or poly-saccharide.

20. The composition according to one of Claims 3 - 19, wherein said pharmaceutical agent is fentanyl or a pharmaceutically acceptable salt thereof.

21. The composition according to Claim 1, wherein said pharmaceutical agent is fentanyl or a pharmaceutically acceptable salt thereof.

22. The composition according to Claim 21, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 5 to about 8.

23. The composition according to Claim 21, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.0 to about 7.4.

24. The composition according to Claim 21, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.1 to about 7.0.

25. The composition according to Claim 21, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6.

26. The composition according to Claim 25, wherein said buffer is a combination of the sodium or potassium salts of phosphoric acid, or a combination of a mono- or di-salt of phosphoric acid and citric acid.

27. The composition according to one of Claims 22 – 26, wherein said pharmaceutically acceptable excipient comprises a polyhydric alcohol.

28. The composition according to one of Claims 22 – 26, wherein said pharmaceutically acceptable excipient comprises a polyhydric alcohol selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof.

29. The composition according to one of Claims 22 – 26, wherein said pharmaceutically acceptable excipient comprises isomalt.

30. The composition according to Claim 1, wherein said buffer is selected from the group consisting of citric acid – sodium hydroxide, citric acid – di-sodium hydrogen phosphate, citric acid – sodium citrate, succinic acid – sodium hydroxide, potassium dihydrogen phosphate – di-sodium hydrogen phosphate, maleic acid disodium salt – hydrochloric acid, potassium dihydrogen phosphate – sodium hydroxide, sodium dihydrogen phosphate – di-sodium hydrogen phosphate, and tris acid maleate – sodium hydroxide.

31. The composition according to Claim 30, wherein said buffer is citric acid – di-sodium hydrogen phosphate, potassium dihydrogen phosphate – di-sodium hydrogen phosphate, maleic acid disodium salt – hydrochloric acid, potassium dihydrogen phosphate – sodium hydroxide, sodium dihydrogen phosphate – di-sodium hydrogen phosphate, and tris acid maleate – sodium hydroxide.

32. The composition according to Claim 1, wherein said pharmaceutical agent is fentanyl, or a pharmaceutically acceptable salt thereof; said buffer is present in an amount sufficient to maintain the pH of said sugar-free dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6; and wherein said sugar-containing oral transmucosal solid dosage form contains sucrose, glucose, or a combination thereof.

33. The composition according to Claim 32, wherein said sugar-containing oral transmucosal solid dosage form contains greater than about 50% by weight sugar, on a dry weight basis.

34. The composition according to Claim 33, wherein said sugar-containing oral transmucosal solid dosage form contains greater than about 90% by weight sugar, on a dry weight basis.

35. The composition according to Claim 1, wherein said pharmaceutical agent is present in said oral transmucosal solid dosage form in an amount of from about 0.0005 to about 50% by weight, on a dry weight basis.

36. The composition according to Claim 35, wherein said pharmaceutical agent is present in said oral transmucosal solid dosage form in an amount of from about 0.005 to about 10% by weight, on a dry weight basis.

37. The composition according to Claim 36, wherein said pharmaceutical agent is present in said oral transmucosal solid dosage form in an amount of from about 0.005 to about 1% by weight, on a dry weight basis.

38. The composition according to Claim 1 further comprising a handle affixed to said sugar-free oral transmucosal solid dosage form.

39. The composition according to Claim 1, wherein said composition is in the form of a compressed powder oral transmucosal solid dosage form.

40. The composition according to Claim 1, wherein said composition is in the form of a hard candy oral transmucosal solid dosage form.

41. The composition according to Claim 1, wherein said composition is in the form of a hard candy oral transmucosal solid dosage form; further comprising a handle affixed to said hard candy oral transmucosal solid dosage form.

42. The composition according to Claim 1, wherein said sugar-containing oral transmucosal solid dosage form contains a buffer.

43. The composition according to Claim 1, wherein said sugar-containing oral transmucosal solid dosage form does not contain a buffer.

44. A sugar-free pharmaceutical composition for the oral transmucosal delivery of fentanyl, said composition comprising fentanyl, or a pharmaceutically acceptable salt form thereof, and a pharmaceutically acceptable excipient, wherein said sugar-free composition is in the form of an oral transmucosal solid dosage form, and wherein said oral transmucosal solid dosage form is bioequivalent to a sugar-containing oral transmucosal solid dosage form.

45. The composition according to Claim 44, wherein said sugar-containing oral transmucosal solid dosage form contains sucrose, glucose, or a combination thereof.

46. The composition according to Claim 44, wherein said sugar-containing oral transmucosal solid dosage form contains greater than about 90% by weight sugar, on a dry weight basis.

47. The composition according to Claim 44, wherein the excipient in said sugar-free composition comprises a polyhydric alcohol.

48. The composition according to Claim 47, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof.

49. The composition according to Claim 48, wherein said polyhydric alcohol is sorbitol.

50. The composition according to Claim 48, wherein said polyhydric alcohol is mannitol.

51. The composition according to Claim 48, wherein said polyhydric alcohol is xylitol.

52. The composition according to Claim 48, wherein said polyhydric alcohol is erythritol.

53. The composition according to Claim 48, wherein said polyhydric alcohol is maltitol.

54. The composition according to Claim 48, wherein said polyhydric alcohol is lactitol.

55. The composition according to Claim 48, wherein said polyhydric alcohol is isomalt.

56. The composition according to Claim 48, wherein said polyhydric alcohol is a combination of mannitol and polyalditol; xylitol and polyalditol; isomalt and polyalditol; mannitol and sorbitol; xylitol and sorbitol; and isomalt and sorbitol.

57. The composition according to Claim 48, wherein said polyhydric alcohol is a combination of isomalt and polyalditol.

58. The composition according to Claim 48, wherein said polyhydric alcohol is a combination of isomalt and sorbitol.

59. The composition according to Claim 44, wherein said excipient comprises a polyhydric alcohol and further comprising a binding agent.

60. The composition according to Claim 59, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof; and said binding agent is selected from the group consisting of polydextrose, cellulosic ether, and polyethylene glycol.

61. The composition according to Claim 59, wherein said polyhydric alcohol is isomalt and said binding agent is selected from the group consisting of polydextrose,

hydroxypropyl cellulose, and polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 3350 to 20,000.

62. The composition according to Claim 59, wherein said polyhydric alcohol is isomalt and said binding agent is polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 4000 to 8000.

63. The composition according to Claim 44, further comprising a buffer in an amount sufficient to maintain a portion of said fentanyl, or pharmaceutically acceptable salt thereof, upon dissolution of said solid oral transmucosal dosage form in saliva, in an ionized state.

64. The composition according to Claim 63, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.0 to about 7.4.

65. The composition according to Claim 63, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.1 to about 7.0.

66. The composition according to Claim 63, wherein said buffer maintains the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6.

67. The composition according to Claim 63, wherein said buffer is selected from the group consisting of citric acid – di-sodium hydrogen phosphate, potassium dihydrogen phosphate – di-sodium hydrogen phosphate, maleic acid disodium salt – hydrochloric acid, potassium dihydrogen phosphate – sodium hydroxide, sodium dihydrogen phosphate – di-sodium hydrogen phosphate, and tris acid maleate – sodium hydroxide.

68. The composition according to Claim 63, wherein said buffer is a combination of the sodium or potassium salts of phosphoric acid, or a combination of a mono- or di-salt of phosphoric acid and citric acid.

69. The composition according to one of Claims 64 - 68, wherein the excipient in said sugar-free composition comprises a polyhydric alcohol.

70. The composition according to one of Claims 64 - 68, wherein the excipient in said sugar-free composition comprises a polyhydric alcohol selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof.

71. The composition according to one of Claims 64 - 68, wherein the excipient in said sugar-free composition is isomalt.

72. The composition according to one of Claims 64 - 68, wherein said excipient comprises a polyhydric alcohol and further comprising a binding agent.

73. The composition according to one of Claims 64 - 68, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, xylitol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof; and said binding agent is selected from the group consisting of polydextrose, cellulosic ether, and polyethylene glycol.

74. The composition according to one of Claims 64 - 68, wherein said polyhydric alcohol is isomalt and said binding agent is selected from the group consisting of polydextrose, hydroxypropyl cellulose, and polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 3350 to 20,000.

75. The composition according to one of Claims 64 - 68, wherein said polyhydric alcohol is isomalt and said binding agent is polyethylene glycol, wherein said polyethylene glycol has an average molecular weight of about 4000 to 8000.

76. The composition according to Claim 44 or 63 further comprising a handle affixed to said sugar-free oral transmucosal solid dosage form.

77. The composition according to Claim 44 or 63 wherein said excipient is in the form of a powder, and said composition is in the form of a compressed powder sugar-free oral transmucosal solid dosage form.

78. The composition according to Claim 44 or 63 wherein said composition is in the form of a hard candy sugar-free oral transmucosal solid dosage form.

79. The composition according to Claim 44, wherein said oral transmucosal solid dosage form contains fentanyl as a fentanyl salt in an amount equivalent to from about 50 μg to about 5000 μg of fentanyl free base.

80. The composition according to Claim 44, wherein said oral transmucosal solid dosage form contains fentanyl as a fentanyl salt in an amount equivalent to from about 50 μg to about 3200 μg of fentanyl free base.

81. The composition according to Claim 44, wherein said oral transmucosal solid dosage form contains fentanyl as a fentanyl salt in an amount equivalent to from about 50 μg to about 2400 μg of fentanyl free base.

82. The composition according to Claim 44, wherein said oral transmucosal solid dosage form contains fentanyl as a fentanyl salt in an amount equivalent to from about 100 μg to about 1600 μg of fentanyl free base.

83. The composition according to Claim 82, wherein said fentanyl salt is fentanyl citrate.

84. The composition according to Claim 83, wherein said excipient comprises a polyhydric alcohol; and further comprising a buffer.

85. The composition according to Claim 84, wherein said excipient comprises isomalt.

86. The composition according to Claim 83, wherein said excipient comprises a polyhydric alcohol selected from the group consisting of sorbitol, mannitol, xylitol, maltitol, lactitol, isomalt, polyalditol, and combinations thereof; and further comprising a binding agent selected from the group consisting of polydextrose, cellulosic ether, and polyethylene glycol; and further comprising a buffer.

87. The composition according to Claim 86, wherein said excipient comprises a isomalt; and the binding agent comprises polyethylene glycol.

88. The composition according to Claim 87 wherein said polyethylene glycol has an average molecular weight of about 3350 to 20,000.

89. The composition according to Claim 87 wherein said polyethylene glycol has an average molecular weight of about 4000 to 8000.

90. The composition according to Claim 89, wherein said buffer is a combination of the sodium or potassium salts of phosphoric acid, or a combination of a mono- or di-salt of phosphoric acid and citric acid.

91. The composition according to Claim 89, wherein said buffer is present in an amount sufficient to maintain the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.1 to about 7.0.

92. The composition according to Claim 89, wherein said buffer is present in an amount sufficient to maintain the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6.

93. The composition according to Claim 92, wherein said oral transmucosal solid dosage form contains fentanyl as fentanyl citrate in an amount equivalent to about 200

μg, about 400 μg, about 600 μg, about 800 μg, about 1200 μg, or about 1600 μg of fentanyl free base.

94. The composition according to Claim 63,
wherein
1) the fentanyl is present as fentanyl citrate in an amount equivalent to 0.016 to 0.126 weight %;
2) the excipient is present in an amount equivalent to 90.88 to 97.98 weight %;
3) the buffer is present in an amount equivalent to 1 to 5 weight % and sufficient to maintain the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6; and
further comprising 4) a lubricant present in an amount equivalent to 0.5 to 2 weight %.

95. The composition according to Claim 63,
wherein
1) the fentanyl is present as fentanyl citrate in an amount equivalent to 0.016 to 0.126 weight %;
2) the excipient is present as isomalt in an amount equivalent to 76.0 to 86.0 weight %;
3) the buffer is present as citric acid in an amount equivalent to 0.5 to 0.6 weight % combined with dibasic sodium phosphate in an amount equivalent to 1.4 to 1.5 weight % and sufficient to maintain the pH of said dosage form, upon dissolution in saliva, at a level of from about 6.3 to about 6.6;
further comprising 4) a binding agent present as polyethylene glycol 8000 in an amount equivalent to 9.5 to 19.0 weight % and
further comprising 5) a lubricant present as magnesium stearate in an amount equivalent to 1.0 weight %.

96. A method for the oral transmucosal delivery of a pharmaceutical agent in a sugar-free dosage form to a patient, comprising providing a composition according to Claim 1, and administering an effective amount of said composition to the oral mucosa of said patient, and delivering said pharmaceutical agent by absorption through a patient's oral mucosal tissue.

97. A method for the oral transmucosal delivery of fentanyl in a sugar-free dosage form to a patient, comprising providing a composition according to Claim 44, and administering an effective amount of said composition to the oral mucosa of said patient, and delivering said pharmaceutical agent by absorption through a patient's oral mucosal tissue.

98. A method of treating pain which comprises introducing into the oral cavity of a patient a therapeutically effective amount of a sugar-free oral transmucosal solid dosage form according to Claim 1 wherein the ionizable pharmaceutical agent is fentanyl, or a pharmaceutically acceptable salt form thereof.

99. The method according to claim 98 in which the pain is breakthrough pain.

100. The method according to claim 98 in which the pain is chronic pain.

101. The method according to claim 98 in which the pain is migraine pain.

102. A method of treating pain which comprises introducing into the oral cavity of a patient a therapeutically effective amount of a sugar-free oral transmucosal solid dosage form according to Claim 44.

103. The method according to claim 102 in which the pain is breakthrough pain.

104. The method according to claim 102 in which the pain is chronic pain.

105. The method according to claim 102 in which the pain is migraine pain.